October 25, 2022

Lyncmed Medical Technology (Beijing) Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K212649
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 26, 2022
Received: September 30, 2022

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212649

Device Name
Disposable Surgical Face Mask

Indications for Use *(Describe)*
The disposable surgical face mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212649

1. Date of Preparation: 10/24/2022

2. Sponsor Identification

Lyncmed Medical Technology (Beijing) Co., Ltd.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Ms. Tingting Su (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Surgical Face Mask
Common Name: Surgical mask

Regulatory Information
Classification Name: Mask, Surgical
Classification: II
Product Code: FXX

Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:

The disposable surgical face mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

Device Description:

The proposed device, Disposable Surgical Face Mask is a three-layer, flat-folded mask. The mask body is made of 25g/m2 polypropylene (PP) non-woven cloth. The mask contains tie strings or ear loop to secure the mask over the users' mouth and face and includes a nosepiece to provide a firm fit over the nose. Ear loops are made of Polyurethane and spandex, and tie strings are made of polypropylene non-woven cloth. The nose clip which is made of Iron-Zinc strip covered by polyethylene terephthalate (PET) covering. The disposable surgical face mask is available in two different specifications: 17.5×9.5cm and 16.5×8.5cm. The device is single use and provided sterile.

5. Identification of Predicate Device

510(k) Number: K202029

Product Name: Medical Surgical Mask

6. Comparison of Technology with Predicate Device

Table 1 Comparison of Surgical Mask

ITEM	Proposed Device K212649	Predicate Device K202029	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The disposable surgical face mask is intended for single use by operating room personnel and	The medical surgical mask is intended for single use by operating room personnel and	Same

	other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	
Mask style	Flat pleated	Flat pleated	Same
Mask color	Blue	Blue	Same
Design feature	Ear loop or tie-on	Ear loop or tie-on	Same
Dimension	175mm×95 mm 165mm×85mm	175mm×95mm 145mm×90mm 120mm×70mm	Difference
Level	Level II	Level II	Same
Fluid Resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	Average 99.9%	Average 98.87%	Difference
Bacterial filtration level	Average 99.9%	Average 99.46%	Difference
Differential pressure	Average 3.63mmH_2O/cm^2	Average 3.72mmH_2O/cm_2	Difference
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
Ear loops	Polyurethane and spandex	Nylon and polyurethane (PU)	Difference
Tie strings	PP non-woven cloth	Nylon	
Nose clip	Iron, zinc and polyethylene (PE) crosslinking material	Iron and polyethylene	
Mask body	25g/m^2 Polypropylene (PP) non-woven cloth	25g/m^2 Polypropylene (PP) non-woven cloth	
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	
Ethylene oxide residuals	EO<4mg/device, ECH<9mg/device	EO<4mg/device, ECH<9mg/device	

Difference- Dimension

The dimension for the proposed device is different from predicate device. This difference does not affect intended use and will not raise any safety issues. In addition, the mask dimension of the proposed device is within the size range of the predicate device.

Difference -Particulate efficiency level

The test result for particulate efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Difference-Bacterial filtration level

The test result for bacteria efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Difference-Differential pressure

The test result for different pressure for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Difference-Patient Contacting Material

The patient contact material for the proposed device is different from predicate device. However, biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- EN 14683:2019 Medical face masks-Requirements and test methods
- CPSC CS-191-53 Flammability Test Method (16 CFR 1610)
- ISO 10993-7:2008 Biological evaluation of medical devices -Part 7: Ethylene oxide sterilization residuals

Table 2 Summary of the Non-clinical Testing

No	Item	Test Method/ Standard	Type	Acceptance Criteria	Results
1	Particulates Filtration Efficiency	ASTM F2299/ F2299M-03(2017)	Ear loop	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: 98.81% Lot 2: 98.78% Lot 3: 98.8%
			Tie-on	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: 98.82% Lot 2: 98.78% Lot 3: 98.79%
2	Bacterial filtration efficiency	ASTM F2101-19	Ear loop	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: 99.9% Lot 2: 99.91% Lot 3: 99.91%
			Tie-on	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: 99.91% Lot 2: 99.9% Lot 3: 99.91%
3	Fluid Resistance	ASTM F1862/ F1826M-17	Ear loop	120 mmHg	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: No penetration at 120 mmHg Lot 2: No penetration at 120 mmHg Lot 3: No penetration at 120 mmHg
			Tie-on	120 mmHg	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: No penetration at 120 mmHg Lot 2: No penetration at 120 mmHg Lot 3: No penetration at 120 mmHg
4	Differential Pressure	EN 14683:2019	Ear loop	$\Delta P<6.0$ mm H_2O/cm^2	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: 3.59 Lot 2: 3.59 Lot 3: 3.59
			Tie-on	$\Delta P<6.0$ mm H_2O/cm^2	Passed 3 non-consecutive lots tested, using a

					sample size of 125/lot Lot 1: 3.61 Lot 2: 3.59 Lot 3: 3.61
5	Flammability	ASTM F2100-19	Ear loop	Class 1	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1
			Tie-on	Class 1	Passed 3 non-consecutive lots tested, using a sample size of 125/lot Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1

Biocompatibility

In accordance with ISO10993-1 the syringe and needle are classified as: contacting intact skin, Limited Contact (< 24hrs). The following testing was conducted:

- Cytotoxicity (ISO 10993-5)
- Irritation (ISO 10993-10)
- Skin Sensitization (ISO 10993-10)

Table 3 Summary of the Biocompatibility testing

No	Item	Test Method/ Standard	Acceptance Criteria	Results
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Pass Under the condition of this study, the device has no potential toxicity.
2	Irritation	ISO 10993-10	Non-irritating	Pass Under the condition of this study, the device has no Irritation.
3	Skin Sensitization	ISO 10993-10	Non-sensitizing	Pass Under the condition of this study, the device has no Sensitization.

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 2 year shelf-life.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in the 510(k) submission, the Disposable Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202029.